

# **The Oncologist's Guide to Synoptic Reporting: A Primer**

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Short Title: The Oncologist's Guide to Synoptic Reporting

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## Abstract

Synoptic reporting in tumour pathology is defined by (1) completeness in terms of data elements as well as (2) a specific, laboratory value-like format. Adoption of synoptic reporting leads to more complete reporting of essential parameters, improved standardization of diagnostic criteria and terminology as well as easier retrieval of information. It is therefore associated with a high degree of satisfaction among end users including surgeons and oncologists and contributes to improvement of clinical care. Furthermore, synoptic reporting is an important step towards higher levels of data capture, which facilitate data exchange and analysis for quality assurance, cancer epidemiology and clinical and basic research.

Increased interest in and adoption of synoptic reporting on a global level is stimulated by the International Collaboration on Cancer Reporting (ICCR) which publishes freely available, evidence-based datasets for reporting an increasing number of different cancer types.

These developments pave a path for increased future application of synoptic reporting across the entire field of oncologic medicine, where it will likely deploy similar benefits as in pathology. Given that synoptic reporting can be considered the most precise means for reporting of medical findings available, it may be predicted to be critical for the promises of precision medicine to become real.

## **The need for complete and standardized reporting in Oncologic Pathology**

Oncologic pathology reports have a key role in diagnostic work-up, therapeutic management and post-therapeutic follow-up of every cancer patient. Given the multidisciplinary nature of current oncologic management, it is natural that various specialists rely on different types of information. These specialists include, but are not limited to medical and radiation oncologists, surgeons, diagnostic and interventional radiologists, nuclear medicine physicians and pathologists themselves. Additional stakeholders include cancer registries, clinical researchers, biobanking experts and quality managers. Furthermore, it is increasingly acknowledged that patients demand access to their reports – which in turn may influence how the information therein should be presented [1].

It would require almost supranatural abilities from a pathologist to keep all these stakeholders in mind when signing out reports and to address their needs – or even to know what all of these actually are in the context of each specific cancer type, histological subtype, type of specimen, tumour stage, eligibility for (neo-) adjuvant therapies, etc.

An additional level of complexity arises from the fact that is insufficient for a pathologist just to describe what they see under the microscope: Cut-offs for a biomarker to be reported as positive or negative may vary depending on the context. For different organs there may be subtle differences in the diagnostic criteria for vascular invasion or in the definition of involvement of surgical margins. Furthermore, these classifications change over time – or there may be competing classifications or definitions at a given time point. Therefore, even a report given by the hypothetical near-supranatural pathologist mentioned above might lead to confusion, when it remains unclear what the underlying classifications and criteria were.

## **Synoptic reporting**

Pathologists have long acknowledged these challenges and recognized *Synoptic Reporting* (derived from ancient Greek “syn-opsis” – overview) as a means to address them[2]. It was realized early on that the decision process which parameters to include was critical and non-trivial [3, 4]. Among a number of institutions, which have published protocols for synoptic reports in the past, two main players have emerged in the past years. The College of American Pathologists (CAP) publishes the most comprehensive set of synoptic cancer protocols as of now [5]. Their use has been mandatory for CAP accredited laboratories which has been a major driver for synoptic reporting in the United States and internationally. More recently, an International Collaboration on Cancer Reporting (ICCR), sponsored by a variety of international pathology organizations, has been launched [6-8]. ICCR has started to publish sets of protocols for various cancer types with the aim to cover the major cancer types. Both CAP and ICCR follow a strictly defined process for dataset development and consultation to ensure a broad consensus, expertise and reflection of the best evidence available.

## **Format of Synoptic Reporting**

Initially, the term “synoptic” simply meant to indicate any structured format other than running text, usually with different data elements mentioned in separate lines [2]. CAP defines SR more narrowly [5], in that synoptic reports must not only encompass a set of required data elements (RDE), but also adhere to a “paired format”, where the designation of each RDE is followed by a “response”. In essence, this is the way how clinical laboratory values are reported (Table 1). Separate RDE must be displayed in separate lines.

Apart from this, CAP accepts a broad variety of possible formats and text markups. Of note, the range of acceptable formats includes low-technology implementations such as filling in and printing the protocols in Microsoft Word format or even photocopying protocols in order to fill them in manually. Similarly, the International Collaboration on Cancer Reporting (ICCR) provides its protocols in portable document format (PDF) which can be printed and filled in manually. CAP specifically permits to present the RDE in any order and to include additional data elements at each institution's and/or pathologist's discretion[5]. Furthermore, additional narrative sections are acceptable.

### **Terminology: safety issues and uniformity**

Neither CAP, nor ICCR have published detailed information on how specific wordings are chosen for data elements or responses. A number of recurrent themes emerges, however, when comparing the various protocols and their development over time: Generally, there is a strong tendency toward uniformity within and across protocols. Positive findings, for example, are usually reported as "present" rather than "yes" or "positive". Similarly, CAP protocols uniformly use the term "extranodal extension" rather than "extracapsular extension".

Negative findings are usually reported as "not identified" rather than "absent" along the line of the statement that "absence of evidence is not evidence of absence" and acknowledging the insight that in medicine the latter can rarely be provided. Of note, biomarkers for which the positive result reflects the normal situation are reported e.g. as "Intact nuclear expression" vs. "Loss of nuclear expression" rather than "positive"/"negative".

Different responses to one data element are usually designed not to differ only by a single word, which might be accidentally omitted and thereby invert the intended meaning, e.g. "not identified" rather than "not present". Also, there is a tendency towards some degree of redundancy, such as in the case of grading, i.e. "G2, moderately differentiated" rather than just "G2".

All of the above conventions aim at minimization of risks associated with misinterpretations of reports. Such considerations should be kept in mind while implementing synoptic protocols locally or translating them to different languages.

### **Advantages of Synoptic Reporting:**

A major advantage of synoptic over narrative reporting is an increase in completeness of data elements, as demonstrated by a number of studies across various cancer types, including – but not limited to – colorectal, lung, breast and prostate cancer as well as cutaneous malignant melanoma [9-16]. One study of cutaneous malignant melanoma found completeness of reports to increase not only in non-specialised, but also in a specialized setting [11]. A meta-analysis on the effects of synoptic reporting [16] found an increase in completeness in 13 out of 14 studies. This increase in completeness is critical, as lack of core data elements may affect quality of cancer care [10, 17]. Of note, the actual rates of completeness achieved by synoptic reporting varies significantly between studies, indicating that the characteristics of implementation may be an important factor. Furthermore, synoptic reporting may contribute to increased awareness of quality indicators and thereby improve quality of pathologic evaluation. Interestingly, the meta-analysis mentioned above [16] found an increase in numbers of lymph nodes obtained from colorectal cancer resections as well as a higher percentage of specimens reaching the minimum of 12 lymph nodes upon introduction of synoptic reporting.

Overall, synoptic reporting is associated with a high degree of satisfaction in pathologists, surgeons and oncologists [18, 19]. This satisfaction seems to be associated with perceived completeness of reports for the purpose of clinical decision making as well as ease of finding relevant information [18] (Figure 1).

### **Limitations of Synoptic Reporting**

The overall high level of satisfaction with synoptic reporting notwithstanding, a similarly recurrent theme across various studies is that pathologists need more time to complete synoptic as compared to narrative reports [18]. Generally, however, the increment in time was moderate and considered acceptable when considering the benefits of synoptic reporting.

An additional issue may be the length of reports. Most of the CAP protocol files extend over several pages, while the more compact format adopted by ICCR may be challenging to render within an existing laboratory information system. In part, increased length of reports is an intrinsic consequence of completeness in terms of RDE as well as of the synoptic format itself. Nevertheless, overly long reports can be avoided by a number of means: First, many RDE are conditional, i.e. they may be mandatory only in a subset of cases (e.g. nuclear grading does not apply to chromophobe renal cell carcinoma). In that case, it is acceptable to omit the pertinent line completely, rather than reporting the RDE as “not applicable”. Second, most CAP and ICCR protocols contain a number of optional data elements, which may or may not be reported at each pathologist’s or institution’s discretion. It may be prudent in this context, to refrain from including “everything”, but rather to keep readability of reports in mind. Along the same line, some hesitation may be advisable with regard to including additional data elements on a local basis.

Finally, synoptic protocols may not fit well very specific circumstances, such as two different histologic tumour types (e.g. carcinoma and lymphoma) occurring in the same resection specimens. Usually, however, such issues can be addressed in a satisfactory manner, and the possibility to include free text provides sufficient flexibility.

### **How to read synoptic reports**

In most instances, synoptic reports should be sufficiently self-explanatory in order to be well understandable to physicians with at least some understanding of the respective medical field. In particular, preferences of individual pathologists with respect to wording should be less of an issue than with narrative reports. Furthermore, as cancer protocols are continuously updated, synoptic reports will usually contain the information required for patient management in current terminology and with sufficient granularity. When very specific information is required, the notes accompanying each cancer or biomarker protocol may be a useful resource. CAP protocols contain a “Notes” section, which gives very detailed information on diagnostic criteria, cut-offs, grading schemes, etc. ICCR protocols are available in bookmarked and hyperlinked versions containing similar information. The respective documents are freely available on the CAP and ICCR websites. Ideally, a synoptic report should contain information, to which version of which protocol it refers. This is of particular relevance with regard to future users, given that classifications change over time.

### **Synoptic reporting on the path towards higher levels of data capture**

As discussed by Ellis and Srigley [20], synoptic reporting has a middle position regarding the degree to which data is structured and is classified as Level 3 in a 6-tiered system:

- Level 1: Narrative report (no defined content)
- Level 2: Narrative report with standardized content (e.g. by using a checklist for dictation)
- Level 3: Synoptic report – adds a specific format, but not necessarily any underlying software implementation
- Level 4: Synoptic report with electronic reporting tools
- Level 5: Standardised structured report with underlying database structure
- Level 6: Standardised structured report with binding terminology in order to facilitate data exchange

According to Ellis and Srigley, implementation of Level 3, primarily benefits immediate clinical needs, while higher levels of data capture are necessary for synoptic reporting to unfold its full potential for pathologists and secondary users. An underlying database structure will allow pathologists to easily monitor statistical distribution of findings and thereby identify potential deviations from expected frequencies, which in turn might point towards issues on a technical or interpretational level.

Ultimately, linking synoptic reports and databases with a uniform terminology, such as SNOMED-CT, will allow third parties including biobanks and cancer registries to access large datasets with unprecedented granularity.

Nevertheless, synoptic reporting according to Level 3 in the Ellison/Srigley classification has an important role within the path towards higher levels of data capture: It serves one particular purpose, i.e. clinicians' needs, already very well. Furthermore, it can be implemented relatively more easily, fast and without major financial implications. Finally, it may be a very significant step on a psychological level, as it trains users to adhere to a standardized format and terminology and fosters precision in reporting.

### **Synoptic reporting in oncology beyond pathology**

While the historic origin and widest application of synoptic reporting are in oncologic pathology, its concepts are spreading non-neoplastic pathology [21, 22] as well as oncologic specialities other than pathology. Main areas of application of synoptic reporting include radiology [23-27] and operative reports in surgery [28-33]. While the overall number of studies addressing the effects of synoptic reporting is considerably lower than in pathology, they tend to show similar outcomes; completeness of reports increases with the use of synoptic reporting, while at the same time the amount of non-essential information is reduced [34-36]. A web-based synoptic reporting tool for thyroid surgery was found to achieve 100% completeness of essential prognostic factors while completeness varied between 3% and >95% for various parameters in descriptive operative reports [37]. Of note, initiatives for synoptic reporting in radiology or oncologic surgery are mostly driven by single academic centres. In contrast to pathology, so far there is only a limited role of national or international

professional or scientific societies. One exception is the American Thyroid Association, which has issued a statement regarding essential elements of perioperative information in relation to thyroid surgery and endorsed use of synoptic operative reports [31].

## **Perspective**

Over more than a quarter of a century, the concept of synoptic reporting in pathology has matured from local initiatives [2] to international standardization with defined processes for design and maintenance of evidence-based reporting templates which are coordinated with the World Health Organization Classification of Tumours [6, 38, 39]. Data is increasingly structured and linked to ontologies such as SNOMED-CT and LOINC [40], facilitating unprecedented levels of integration with the potential to revolutionize their use with regard to clinical care, quality assurance, as well as clinical and basic research [41].

This development paves a path for future widespread applications of synoptic reporting (and higher levels of data capture) in other fields in oncology. Not only do the forces, which have driven this development in pathology – the need for complete, accurate and standardized information – act on all oncologic specialties, but also can synoptic reporting be predicted to be a major part of the respective solutions. Experience from pathology shows that high quality, evidence-based and timely consensus forms for reporting and their endorsement by national and international professional and scientific societies are critically important facilitators for widespread application of synoptic reporting.

For precision medicine not to remain an empty promise, precision has to be the *modus operandi* in the entire practice of oncologic medicine and synoptic reporting is the most precise type of communication available to us.

## **Statement of Ethics**

The author has no ethical conflicts to disclose.

## **Disclosure Statement**

The author has no conflicts of interest to declare.

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**Table**

Narrative	Synoptic
Upon incubation with the patient's serum, immunofluorescence microscopy shows staining of neutrophils in a perinuclear pattern. This is still visible when the serum is diluted 1:320, but not at 1:640 dilution	ANCA: positive (p-ANCA); Titer 1:320
<i>The synoptic format of data element, paired with a response recapitulates the way clinical laboratory values are reported. This example of immunofluorescence illustrates that it would appear unusual to physicians to receive such test results in narrative text, even though there may be a similar type of analysis underlying the test result.</i>	
... with lymph node metastases detected in 3 out of 12 lymph nodes, largest diameter 1.2 cm, without evidence of extracapsular extension ...	Number of lymph nodes submitted: 12 Number of lymph nodes involved: 3 Largest diameter of lymph node metastasis: 1.2cm Extranodal extension: not identified
<i>Example of typical elements from a surgical pathology report. Most readers would likely find it more easy to extract a particular piece of information from the synoptic as compared to the narrative report.</i>	
15% of tumour cells are positive for Mum-1.	Mum-1 (immunostaining): negative
15% of tumour cells are positive for p53.	p53 (immunostaining): wildtype pattern
15% of tumour cells are positive for Ki-67.	Ki-67 proliferation index: 15%
<i>In particular for biomarkers, specific criteria may have to be applied for interpretation of a given finding. 15% of stained tumour cell nuclei would not qualify for Mum-1 expression in the context of the Hans Algorithm for determining cell of origin in diffuse large B cell lymphoma. Depending on how the immunostaining is set up, 15% of nuclear p53 staining would likely indicate wildtype TP53. In contrast, for Ki-67 the percentage of positive nuclei is reported (with specific recommendations on how many nuclei to count for some tumour types).</i>	

Table 1. Examples of information that might be found in laboratory or pathology reports in narrative and synoptic format.

## Figure

Lung, upper lobe, right, lobectomy:

Single focus (greatest tumor diameter 3.2 cm) of an invasive adenocarcinoma with acinar (80%) and solid (20%) growth patterns, localized in the upper lobe, with visceral pleura invasion, without lymphovascular invasion. No adjacent structures present. All margins uninvolved by carcinoma (including bronchial, vascular and parenchymal margins). Minimal distance of invasive carcinoma from margin is 1.8cm (from the bronchial margin). No known history of presurgical therapy. Mild emphysematous alterations of non-neoplastic pulmonary tissue.

### Synoptic Report (Lung, Resection)

Procedure laterality, tumor site: lobectomy, right, upper lobe

Tumor size: 3.2cm

Tumor focality: Single tumor

Histologic type: Invasive adenocarcinoma, acinar predominant (80%)

Other subtypes present: solid (20%)

Visceral Pleura Invasion: present

Lymphovascular invasion: not identified

Direct invasion of adjacent structures: No adjacent structures present

Margins: All margins uninvolved by carcinoma

Distance of carcinoma from closest margin: 1.8cm (Bronchial Margin)

Margins examined: Bronchial, Vascular, Parenchymal

Treatment effect: No known presurgical therapy

Figure 1. Color-coded representation of data elements (according to the College of American Pathologists template for lung cancer) in narrative (top) and synoptic (bottom) formats. Even when complete in terms of required data elements, narrative reports tend to be shorter than synoptic reports. Finding a particular piece of information, however, is easier with the synoptic format. As in this example, narrative reports tend to include more non-essential data of little clinical relevance (mild emphysematous change) than synoptic reports, while essential data elements are often incomplete.